General

Guideline Title

The prevention of early-onset neonatal group B streptococcal disease.

Bibliographic Source(s)

Money D, Allen VM, Infectious Disease Committee. The prevention of early-onset neonatal group B streptococcal disease. J Obstet Gynaecol Can. 2013 Oct;35(10):939-51. [73 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Dobson S, Money D. The prevention of early-onset neonatal group B streptococcal disease. Society of Obstetricians and Gynaecologists of Canada clinical practice guideline, No. 149, September 2004. J Soc Obstet Gynaecol Can 2004;26:826-32.

Recommendations

Major Recommendations

The quality of evidence (I-III) and classification of recommendations (A-E, L) are defined at the end of the "Major Recommendations."

Risk-Based Versus Screening Approach

Recommendations

1. Offer all women screening for colonization with group B streptococcus (GBS) at 35 to 37 weeks' gestation with culture taken from one swab first to the vagina and then to the rectum (through the anal sphincter). (II-1A) This includes women with planned Caesarean delivery because of their risk of labour or ruptured membranes earlier than the scheduled Caesarean delivery. (II-2B)
2. Because of the association of heavy colonization with early onset neonatal disease, provide intravenous antibiotic prophylaxis for GBS at the onset of labour or rupture of the membranes to:
    - Any woman positive for GBS by vaginal/rectal swab culture screening done at 35 to 37 weeks' gestation (II-2B)
    - Any woman with an infant previously infected with GBS (II-3B)
    - Any woman with documented GBS bacteriuria (regardless of level of colony-forming units) in the current pregnancy (II-2A)
3. Manage all women who are <37 weeks' gestation and in labour or with rupture of membranes with intravenous GBS antibiotic prophylaxis for a minimum of 48 hours, unless there has been a negative vaginal/rectal swab culture or rapid nucleic acid-based test within the previous 5 weeks. (II-3A)
4. Treat all women with intrapartum fever and signs of chorioamnionitis with broad spectrum intravenous antibiotics targeting chorioamnionitis and including coverage for GBS, regardless of GBS status and gestational age. (II-2A)

Practical Aspects of the Screening Methods

Recommendation

5. Request antibiotic susceptibility testing on GBS-positive urine and vaginal/rectal swab cultures in women who are thought to have a significant risk of anaphylaxis from penicillin. (II-1A)

Pre-Labour Rupture of Membranes

Summary Statement

There is good evidence based on randomized control trial data that in women with pre-labour rupture of membranes at term who are colonized with GBS, rates of neonatal infection are reduced with induction of labour (I). There is no evidence to support safe neonatal outcomes with expectant management in this clinical situation.

Recommendations

6. If a woman with pre-labour rupture of membranes at ≥37 weeks' gestation is positive for GBS by vaginal/rectal swab culture screening, has had GBS bacteriuria in the current pregnancy, or has had an infant previously affected by GBS disease, administer intravenous GBS antibiotic prophylaxis. Immediate obstetrical delivery (such as induction of labour) is indicated, as described in the Induction of Labour guideline published by the Society of Obstetricians and Gynaecologist of Canada (SOGC) in September 2013 (see the National Guideline Clearinghouse [NGC] summary of the SOGC guideline Induction of Labour). (II-2B)
7. At ≥37 weeks' gestation, if GBS colonization status is unknown and the 35- to 37-week culture was not performed or the result is unavailable and the membranes have been ruptured for greater than 18 hours, administer intravenous GBS antibiotic prophylaxis. (II-2B)
8. If a woman with pre-labour rupture of membranes at <37 weeks' gestation has an unknown or positive GBS culture status, administer intravenous GBS prophylaxis for 48 hours, as well as other antibiotics if indicated, while awaiting spontaneous or obstetrically indicated labour. (II-3B)

Definitions:

Quality of Evidence Assessment*

I: Evidence obtained from at least one properly randomized controlled trial

II-1: Evidence from well-designed controlled trials without randomization

II-2: Evidence from well-designed cohort (prospective or retrospective) or case–control studies, preferably from more than one centre or research group

II-3: Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category

III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

*Adapted from The Evaluation of Evidence criteria described in the Canadian Task Force on Preventive Health Care.

Classification of Recommendations†

A. There is good evidence to recommend the clinical preventive action

B. There is fair evidence to recommend the clinical preventive action

C. The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making

D. There is fair evidence to recommend against the clinical preventive action

E. There is good evidence to recommend against the clinical preventive action

L. There is insufficient evidence (in quantity or quality) to make a recommendation; however, other factors may influence decision-making

†Adapted from the Classification of Recommendations criteria described in the Canadian Task Force on Preventive Health Care.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Early-onset neonatal group B streptococcal disease

Guideline Category

Prevention

Risk Assessment

Screening

Treatment

Clinical Specialty

Infectious Diseases

Obstetrics and Gynecology

Pediatrics

Preventive Medicine

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To review the evidence in the literature and to provide recommendations on the management of pregnant women in labour for the prevention of early-onset neonatal group B streptococcal disease

Target Population

- Pregnant women
- Newborn infants

Interventions and Practices Considered

1. Screening for colonization with group B streptococcus (GBS) at 35 to 37 weeks' gestation
2. Intravenous GBS antibiotic prophylaxis
3. Broad spectrum intravenous antibiotics targeting chorioamnionitis and including coverage for GBS (for women with intrapartum fever and signs of chorioamnionitis)
4. Antibiotic susceptibility testing
5. Obstetrical delivery

Major Outcomes Considered

Maternal Outcomes

- Exposure to antibiotics in pregnancy and labour
- Complications related to antibiotic use

Neonatal Outcomes

Rates of early-onset group B streptococcal infections

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

Published literature was retrieved through searches of MEDLINE, CINAHL, and The Cochrane Library from January 1980 to July 2012 using appropriate controlled vocabulary and key words (group B streptococcus, antibiotic therapy, infection, prevention). Results were restricted to systematic reviews, randomized control trials/controlled clinical trials, and observational studies. There were no date or language restrictions. Searches were updated on a regular basis and incorporated in the guideline to May 2013. Grey (unpublished) literature was identified through searching the websites of health technology assessment and health technology-related agencies, clinical practice guideline collections, clinical trial registries, and national and international medical specialty societies.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of Evidence Assessment*

I: Evidence obtained from at least one properly randomized controlled trial

II-1: Evidence from well-designed controlled trials without randomization

II-2: Evidence from well-designed cohort (prospective or retrospective) or case–control studies, preferably from more than one centre or research

group

II-3: Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category

III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

*Adapted from The Evaluation of Evidence criteria described in the Canadian Task Force on Preventive Health Care.

Methods Used to Analyze the Evidence

Systematic Review

Description of the Methods Used to Analyze the Evidence

The quality of evidence in this document was rated using the criteria described in the Report of the Canadian Task Force on Preventive Health Care (see the "Rating Scheme for the Strength of the Evidence" field).

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Not stated

Rating Scheme for the Strength of the Recommendations

Classification of Recommendations†

A. There is good evidence to recommend the clinical preventive action

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C. The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making

D. There is fair evidence to recommend against the clinical preventive action

E. There is good evidence to recommend against the clinical preventive action

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†Adapted from the Classification of Recommendations criteria described in the Canadian Task Force on Preventive Health Care.

Cost Analysis

- Economic analyses of risk-based and universal culture-based approaches have been conducted and showed that universal culture-based is equivalent in cost to risk-based approach if one considers the cost savings involved with reduction of morbidity and mortality. It has also been shown that a risk-based versus screening approach is essentially equivalent in cost and in the number of women receiving antibiotics prophylaxis.
- A study comparing the estimated direct costs (including screening test costs and hospital costs) and consequences of intrapartum polymerase chain reaction (PCR) screening for early-onset group B streptococcus (GBS) disease (Xpert GBS test) with antenatal lower vagina culture screening demonstrated a higher detection rate of GBS colonization with PCR (16.7% versus 11.7%). The average total cost

per delivery was US$1759 ± 1209 for antenatal screening in 2009 and $1754 ± 842 for intrapartum screening in 2010 (*P*=0.9). With improved techniques, therefore, in some institutions GBS screening may be replaced by intrapartum PCR assessment.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

This Clinical Practice Guideline has been prepared by the Infectious Disease Committee, reviewed by the Infectious Diseases and Immunization and the Fetus and Newborn Committees of the Canadian Paediatric Society, and the Society of Obstetricians and Gynaecologists of Canada (SOGC) Family Practice Advisory Committee, and approved by the Executive and Council of the Society of Obstetricians and Gynaecologists of Canada.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Prevention of early-onset neonatal group B streptococcal disease, thereby reducing complications such as incidence of preterm labour and preterm pre-labour rupture of membranes

Potential Harms

- Concern that the use of antibiotics for group B streptococcus (GBS) prophylaxis may result in the selection of other organisms such as *Escherichia coli (E. coli)* is certainly an issue in theory; however, a study of trends in neonatal sepsis has been reassuring, with no increase in the rate of neonatal sepsis overall in the post-GBS prophylaxis era, but some increase in *E. coli* sepsis in preterm or low-birth-weight infants only.
- Antibiotic resistance
- The risk of allergic or anaphylactic reaction to penicillins is between 4 per 10 000 and 4 per 100 000. For first-generation cephalosporins, the risk of cross-reaction with penicillins is 0.5%; the risk with second- and third-generation cephalosporins appears to be even lower.
- Disadvantages of polymerase chain reaction (PCR) screening are the lack of antibiotic susceptibility data, potentially false-negative results related to rupture of membranes, and the fact that there is insufficient time for use of selective enrichment broth for at least 4 hours prior to PCR in the intrapartum setting.

Qualifying Statements

Qualifying Statements

This document reflects emerging clinical and scientific advances on the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed. Local institutions can dictate amendments to these opinions.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Foreign Language Translations

Patient Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2004 Sep (revised 2013 Oct)

Guideline Developer(s)

Society of Obstetricians and Gynaecologists of Canada - Medical Specialty Society

Source(s) of Funding

Society of Obstetricians and Gynaecologists of Canada

Guideline Committee

Infectious Diseases Committee

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

Disclosure statements have been received from all members of the committees.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Dobson S, Money D. The prevention of early-onset neonatal group B streptococcal disease. Society of Obstetricians and Gynaecologists of Canada clinical practice guideline, No. 149, September 2004. J Soc Obstet Gynaecol Can 2004;26:826-32.

Guideline Availability

Electronic copies: Available from the Society of Obstetricians and Gynaecologists of Canada Web site . Also available in French from the SOGC Web site .

Print copies: Available from the Society of Obstetricians and Gynaecologists of Canada, La société des obstétriciens et gynécologues du Canada (SOGC) 780 promenade Echo Drive Ottawa, ON K1S 5R7 (Canada); Phone: 1-800-561-2416.

Availability of Companion Documents

None available

Patient Resources

The following is available:

- Group B streptococcus (GBS) infection in pregnancy. Women's health information. Electronic copies: Available from the Society of Obstetricians and Gynaecologists of Canada (SOGC) Web site . Also available in French from the SOGC Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI Institute on January 31, 2014. The information was verified by the guideline developer on March 17, 2014.

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